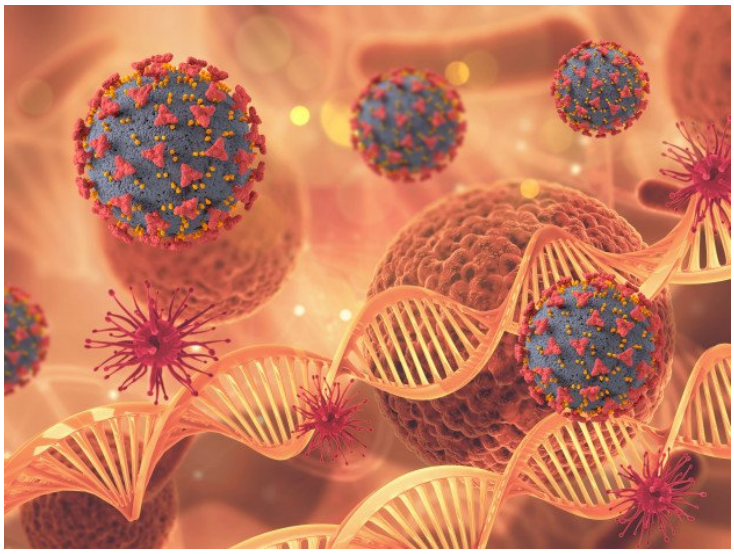
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

FDA approves first CRISPR test for coronavirus detection

May 13, 2020 | News

Sherlock Biosciences's CRISPR SARS-CoV-2 Rapid Diagnostic kit with the detection time of 1 hour receives FDA Emergency Use Authorization in the United States



US based Sherlock Biosciences, an Engineering Biology company dedicated to making diagnostic testing better, faster and more affordable, announced on 7 May 2020 that the company has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its Sherlock™ CRISPR SARS-CoV-2 kit for the detection of the virus that causes COVID-19, providing results in approximately one hour. It's the first emergency-use approval from The US drug regulator to detect coronavirus using gene-editing technology CRISPR.

The Sherlock™ CRISPR SARS-CoV-2 test kit is designed for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Based on the SHERLOCK method, which stands for **S**pecific **H**igh-sensitivity **E**nzymatic **R**eporter un**LOCK**ing, the kit works by programming a CRISPR molecule to detect the presence of a specific genetic signature of SARS-CoV-2 in nasal swab, nasopharyngeal swab, oropharyngeal swab or bronchoalveolar lavage (BAL) specimen. When the signature is found, the CRISPR enzyme is activated and releases a detectable signal. If the virus's genetic material is found, a CRISPR enzyme generates a fluorescent glow.

In addition to SHERLOCK, the company is also developing its INSPECTR™ platform to create an instrument-free, handheld test – similar to that of an at-home pregnancy test – that utilizes Sherlock Biosciences' Synthetic Biology platform to provide rapid detection of a genetic match of the SARS-CoV-2 virus.

"SHERLOCK enables rapid identification of a single alteration in a DNA or RNA sequence in a single molecule. That precision, coupled with its capability to be deployed to multiplex over 100 targets or as a simple point-of-care system, will make it a critical addition to the arsenal of rapid diagnostics already being used to detect COVID-19" says Sherlock Biosciences co-founder and board member, David R. Walt, Ph.D., who co-leads the Mass General Brigham Center for

COVID Innovation.

“While it has only been a little over a year since the launch of Sherlock Biosciences, today we have made history with the very first FDA-authorized use of CRISPR technology, which will be used to rapidly identify the virus that causes COVID-19. We are committed to providing this initial wave of testing kits to physicians, laboratory experts and researchers worldwide to enable them to assist frontline workers leading the charge against this pandemic” says Rahul Dhanda, co-founder, president and CEO of Sherlock Biosciences.